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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,754	07/23/2003	Steven M. Leventer	JAN-027 CON	8132

7590 08/16/2004

Vela Pharmaceuticals
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Collegeville, PA 19426

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,754	LEVENTER ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date N/A - from parent application 2/7/2002
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-5 AND 28-32 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment filed July 23, 2003 has been received and entered into the application. Applicants' indicated that claims 6-28 should be canceled and claims 29-33 be added. However, as originally filed, the present application did not contain a claim numbered as 28. As per 37 C.F.R. 1.126, claims 29-33 have been renumbered as 28-32, respectively. Accordingly, claims 6-27 have been canceled and claims 28-32 have been added.

Applicants' Information Disclosure Statement filed in parent application Serial No. 10/008,516 on November 8, 2001 has been transferred to the instant application. As reflected by the attached, newly signed copies of form PTO-1449, the cited references have been considered by the Examiner.

Specification

The disclosure is objected to because of the following informality:

The following information needs to be incorporated into the specification at page 1, line 1 – "This application is a continuation of application Serial No. 10/008,516, filed November 8, 2001, now U.S. Patent No. 6,649,607".

Appropriate correction is required.

Claim Objection

Claim 32 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In claim 32, which is directed to a composition an depends from a claim directed to a composition, "administered" is a method limitation and "30 mg/kg" represents a rate of administration, also a method limitation.

Applicants are required to either cancel the claim or amend the claim to place it in proper dependent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 28 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Landry et al. (U.S. Patent No. 6,080,736, cited by Applicants) who teach a pharmaceutical composition that comprises 95%+ pure S-tofisopam (col. 20, line 61-62), 2% tween and 5% DMSO and distilled water (Table 1 at col. 20). Insofar as the purity is reported as with a "+" suffix, it is believed that such placed the requirements of claim 5 into the possession of the public.

Also, respecting claim 29, assuming an average rat weight of from 250g to 300g and an administration rate of 30mg/kg, such would equate to a dosage, i.e., a composition, comprising from 7.5 mg to 9 mg of S-tofisopam. This amount is not seen to be distinct from the claimed amount of "approximately 10 mg...".

Claims 30-31 are not subject to this rejection or a rejection based on 35 U.S.C. 103 because the dosage amounts required therein are clearly above those that would have been in the reference compositions. Also, because S-tofisopam is not the active agent of

the reference and is merely administered for comparative effects, no motivation is present to have altered the dosage amounts of S-tofisopam disclosed by the patentees.

Claim 32 is not subject to this rejection because the "dosage" requirements set forth therein are not those of a composition claim and thus the Examiner cannot reasonably ascertain whether or not the claimed "dosage amounts" are actually disclosed in the reference.

Double Patenting

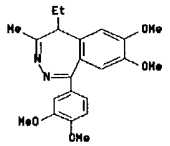
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional

Claims 1-5 and 28-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending Application No. 10/781,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because S-tofisopam having the general structure:



is clearly encompassed by the co-pending claims.

Further, because the present claims recite "comprising", the additional active agents of the co-pending claims are not excluded by the present claims.

Also, in the co-pending claims, the dosage amount, isomeric purity or dosage form is not limited and thus would have encompassed those values or dosage forms designations presently claimed or else such values or dosage forms would have been obvious determinations to the skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Non-Provisional

Claims 1-5 and 28-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,649,607. Although the conflicting claims are not identical, they are not patentably distinct from each other because the determination of the isomeric purity, dosage amounts and dosage forms to employ would have been a matter well within the purview of the skilled artisan and the artisan would have been motivated to do so in order to provide the purist, most effective dosage amounts and form possible.

The present claims recite "comprising" and thus do not patentably exclude the addition active agents of the patented claims.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

August 4, 2004